Translation

PCT Application
PCT/JP2003/007071

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference C1-A0210Y1P	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP03/07071	International filing date (*day/month/year*) 04 June 2003 (04.06.03)	Priority date (*day/month/year*) 05 June 2002 (05.06.02)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, 5/16, C07K 16/08, A01K 67/027		
Applicant CHUGAI SEIYAKU KABUSHIKI KAISHA		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☒ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 04 June 2003 (04.06.03)	Date of completion of this report 21 November 2003 (21.11.2003)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

Form PCT/IPEA/409 (cover sheet) (July 1998)

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I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed

☐ the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the drawings:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos. _____

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.3

The common feature among claims 1-19 is a transgenic non-human animal having a gene that codes the membrane protein from a virus inserted therein.

However, a transgenic mouse having a gene that codes the membrane protein from a virus inserted therein was well known on the priority date of the present application (refer to J. SATOI et al., J. Virol., 2001, Vol. 75, No. 24, pages 12121-12127). Consequently, this common feature does not define a contribution over the prior art; therefore, it cannot be said to be a special technical feature as prescribed by PCT Rule 13.2.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11, 13, 14, 17-19	YES
	Claims	12, 15, 16	NO
Inventive step (IS)	Claims	1-11, 19	YES
	Claims	12-18	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations

Document 1: J. SATOI et al., J. Virol., 2001, Vol. 75, No. 24, pages 12121-12127

Document 2: G. W. BLISSARD et al., Virology, 1989, Vol. 170, No. 2, pages 537-555

Document 3: R. LIANG et al., J. Biol. Chem., 1995, Vol. 270, No. 12, pages 6456-6463

Claims 12, 15 and 16

The invention set forth in claims 12, 15 and 16 lacks novelty in the light of document 1.

Document 1 discloses a transgenic mouse having a plasmid inserted therein, said plasmid having been modified with the gene that codes the envelope protein of HCV, which is a membrane protein from a virus.

Claims 12-18

The inventions set forth in claims 12-18 do not involve an inventive step in the light of document 2.

Document 2 discloses the amino acid sequence for the membrane protein gp64 and the base sequence that codes said protein, and confirms the ability to express gp64 using a transformed cell.

The feature of creating of a transgenic mouse having DNA with a known base sequence or amino acid sequence

inserted therein was well known on the priority date of the present application; therefore, it would be possible to create a transgenic mouse having the gene that codes gp64, which is disclosed in document 1, inserted therein.

Claims 1-11 and 19

The inventions that are set forth in claims 1-11 and 19 are not disclosed in the documents that are cited in the international search report or in the documents that are considered to be related to the inventions in question, and could not have been invented by simply combining the disclosures of these documents.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The inventions set forth in claims 1-7, 9-13 and 15-18 pertain to a "method for producing antibodies that recognize a target antigen, which comprises a step for obtaining the antibody to a target antigen or the gene that codes the antibody by immunizing a non-human animal that exhibits an immunological tolerance to background antigens with an immunogen that includes the target antigen and background antigens." However, the only specific example of the abovementioned antigen production method in the description involves obtaining a transgenic mouse using gp64 as the background antigen, and producing the antibody to PepT1 in said transgenic mouse.

Consequently, in the light of the abovementioned disclosure in the description, there is not sufficient support in the description for the feature of creating a non-human animal that exhibits immunological tolerance to any background antigen and obtaining the antibody to any intended antigen using said non-human animal that exhibits immunological tolerance in the inventions set forth in the abovementioned claims.